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Atty Docket No. 020048-002000US

PTO FAX NO.: 1-571-273-8300

ATTENTION: Examiner Jyoti Nagpaul Group Art Unit 1743

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EXAMINER Jyoti Nagpaul

CERTIFICATION OF FACSIMILE TRANSMISSION

I hereby certify that the following documents in re Application of Douglas B. Dority, Application No. 10/084,409, filed February 25, 2002 for FLUID PROCESSING AND CONTROL are being facsimile transmitted to the Patent and Trademark Office on the date shown below.

Documents Attached

1. APPELLANT'S BRIEF UNDER 37 CFR §41.37

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By: _____

PATENT
Attorney Docket No.: 020048-002000US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of:	Examiner: NAGPAUL, JYOTI
DOUGLAS B. DORITY ET AL.	Art Unit: 1743
Application No.: 10/084,409	Confirmation No.: 8156
Filed: Feb. 25, 2002	APPELLANT'S BRIEF UNDER 37 CFR §41.37
For: FLUID PROCESSING AND CONTROL	

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Commissioner for Patents
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Sir:

This amended Appeal Brief is filed pursuant to 37 C.F.R. §41.37, following the Notice of Non-Compliant Appeal Brief mailed May 22, 2007. Specifically, the Status of the Claims has been amended to give reference to the status of all the claims as required under 37 C.F.R. §41.37(c)(1)(iii). Furthermore, the grounds of the rejection to be reviewed on appeal has been amended to list claims 44 and 45 as required under 37 C.F.R. §41.37(c)(1)(vi-vii). Accordingly, this appeal brief is believed to be proper.

TABLE OF CONTENTS

I. REAL PARTY IN INTEREST

The real party in interest for the above-identified application is CEPHEID, a California corporation having its principal place of business at 904 Caribbean Drive, Sunnyvale, California 94089. The assignment was recorded in the U.S. Patent and Trademark Office on Feb. 25, 2002 at Reel 012663/Frame 0899.

II. RELATED APPEALS AND INTERFERENCES

There are no appeals or interferences related to the present appeal.

III. STATUS OF CLAIMS

Claims 1-16 and 26-48 are rejected, claims 17-25 are canceled. Claims 1-16 and 26-48 are pending and presently being appealed.

Claims 1, 12, 26-27, 30-32, 34-37, 42-43, and 46 stand rejected under 35 U.S.C. §102(b) as being anticipated by Gundelfinger (US 4,068,528). Claims 44 and 45, while not specifically rejected under 35 U.S.C. §102(b) as anticipated by Gundelfinger, depend from claims 26 and 43 that are specifically rejected under 35 U.S.C. §102(b) as being anticipated by Gundelfinger.

Dependent claims 2-11, 13-16, 28-29, 33, and 47-48 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Gundelfinger in view of Sakai (US 4,937,048).

Dependent claims 38-41 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Gundelfinger in view of Lecerf (US 4,705,059).

IV. STATUS OF AMENDMENTS

Applicants filed a Response under 37 C.F.R. §1.116 on April 11, 2005. No amendments were made, except claims 17-25 were withdrawn as drawn to a non-elected species of invention. A Final Action mailed February 17, 2006, indicated that the Response did not place the application in condition for allowance.

In accordance with 37 C.F.R. § 1.192(c)(9), a copy of the claims involved in the appeal are contained in the Appendix attached hereto.

V. SUMMARY OF CLAIMED SUBJECT MATTER

This application discloses a fluid control and processing system (claims 1-16 and 26-48).

In the embodiment of independent claim 1, described on page 2, lines 3-15 of the specification, and as illustrated in Figs. 1-23, discloses a fluid control and processing system comprising a housing having a plurality of chambers and a valve body. The valve body includes a first fluid processing region continuously coupled fluidicly with a fluid displacement region, the fluid displacement region being depressurizable to draw fluid into the fluid displacement region and pressurizable to expel fluid from the fluid displacement region. The valve body also includes a plurality of external ports, the first fluid processing region being fluidicly coupled with at least two of the external ports, the fluid displacement region being fluidicly coupled with at least one of the external ports of the valve body, and the valve body being adjustable with respect to the housing to allow the external ports to be placed selectively in fluidic communication with the plurality of chambers. At least one of the plurality of chambers is a processing chamber, the processing chamber including a first port and a second port for selectively communicating with at least one of the external ports of the valve body, and the processing chamber providing an additional fluid processing region.

In the embodiment of independent claim 26, described on page 2, line 33 to page 3, line 10 of the specification, and as illustrated in Figs. 25-26EE, discloses a fluid control and processing system comprising a housing having a plurality of chambers and a valve body. The valve body includes a fluid processing region continuously coupled fluidicly with a fluid displacement region, the fluid displacement region being depressurizable to draw fluid into the fluid displacement region and pressurizable to expel fluid from the fluid displacement region. The valve body also includes an external port, the fluid processing region being fluidicly coupled with the external port, the fluid displacement region being fluidicly coupled with the external port of the valve body, and the valve body being adjustable with respect to the housing to allow the external port to be placed selectively in fluidic communication with the plurality of chambers.

In the embodiment of independent claim 46, described on page 4, lines 23-32, and as illustrated in Figs. 25-26EE, discloses a fluid control and processing system for controlling fluid flow among a plurality of chambers. The system comprises a body including a fluid processing region continuously coupled fluidicly with a fluid displacement region. The fluid displacement region is depressurizable to draw fluid into the fluid displacement region and

pressurizable to expel fluid from the fluid displacement region. The body includes at least one external port, the fluid processing region being fluidicly coupled with the at least one external port, and the fluid displacement region being fluidicly coupled with at least one external port of the valve body. The body is rotatably adjustable relative to the plurality of chambers to place the at least one external port selectively in fluidic communication with the plurality of chambers.

VI. GROUNDS OF REJECTION PRESENTED FOR REVIEW

A. Claims 1, 12, 26-27, 30-32, 34-37, 42-43, and 46 stand rejected under 35 U.S.C §102(b) as being anticipated by Gundelfinger (U.S. Pat. No. 4,068,528). Applicant notes that claims 44 and 45, while not specifically rejected under 35 U.S.C. §102(b), depend from claims 26 and 43 that are specifically rejected under 35 U.S.C. §102(b).

B. Claims 2-11, 13-16, 28-29, 33, and 47-48 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Gundelfinger (U.S. Pat. No. 4,068,528) in view of Sakai (U.S. Pat. No. 4,937,048).

C. Claims 38-41 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Gundelfinger in view of Lecerf (U.S. Pat. No. 4,705,059).

VII. ARGUMENTS

A. Independent claims 1, 26 and 46 are not properly rejected under 35 U.S.C. §102(b) as being anticipated by Gundelfinger (U.S. Pat. No. 4,068,528).

Applicant respectfully submits that independent claims 1, 26 and 46 are novel and patentable over Gundelfinger because, for instance, Gundelfinger does not disclose or suggest a housing having a plurality of chambers and a valve body having a fluid processing region coupled fluidicly with a fluid displacement region.

Applicant respectfully disagrees with the Examiner's contention that Gundelfinger shows a plurality of chambers F1-F6. Actually, F1-F6 in Gundelfinger are internal flow passages in a stator that Gundelfinger teaches are very small holes (e.g., 0.010 inches in diameter) in the stator (column 9, lines 8-9). Even if one tried to construe these holes in the stator as a "plurality of chambers", Gundelfinger's device still lacks a valve body having a fluid processing region. Applicant respectfully disagrees with the Examiner's contention that Gundelfinger shows a valve body having a fluid processing region 30. Actually, reference

numeral 30 in Gundelfinger is a sample loop formed by a piece of tubing that Gundelfinger specifically teaches is external to the valve (column 6, line 31). Thus, Gundelfinger does not teach or suggest a valve body having a fluid processing region coupled fluidicly with a fluid displacement region. Instead, Gundelfinger specifically teaches a very different structure in which a sample loop is external to a valve. Because Gundelfinger does not teach or suggest a valve body having a fluid processing region coupled fluidicly with a fluid displacement region as explicitly recited by applicants in independent claims 1, 26, and 46, Gundelfinger does not anticipate the claims.

The arguments presented above also apply to claim 12 that depends from independent claim 1 and claims 27, 30-32, 34-37, and 42-45 that depend directly or indirectly from independent claim 26.

B. Dependent claims 2-11, 13-16, 28-29, 33, and 47-48 are not properly rejected under 35 U.S.C. §103(a) as being obvious in light of Gundelfinger (U.S. Pat. No. 4,068,528) in view of Sakai (U.S. Pat. No. 4,937,048).

The Examiner bears the burden of establishing a *prima facie* case of obviousness. *In re Rijckaert*, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993); *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). Only if this burden is met does the burden of coming forward with rebuttal arguments or evidence shift to the applicant. *Rijckaert*, 9 F.3d at 1532, 28 USPQ2d at 1956. When the references cited by the Examiner fail to establish a *prima facie* case of obviousness, the rejection is improper and will be overturned. *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988)." See *In re Deuel*, 51 F.3d 1552, 34 USPQ2d 1210, 1214 (Fed. Cir. 1995).

In order to establish a proper *prima facie* case of obviousness, the rejection must demonstrate that (1) the cited references teach all the claimed elements; (2) there is a suggestion or motivation in the prior art to modify or combine the reference teachings; and (3) a reasonable expectation of success. MPEP § 2143; *In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991).

Here, claims 2-11 and 13-16 depend either directly or indirectly from independent claim 1, and therefore include all of the limitations of independent claim 1. As discussed above (in argument (A)) Gundelfinger does not anticipate claim 1, because Gundelfinger does not teach

or disclose all of the salient elements of the independent claim. In particular, Gundelfinger does not teach or suggest 1) a plurality of chambers, or 2) a valve body having a fluid processing region coupled fluidicly with a fluid displacement region as explicitly recited by applicants in independent claim 1. Sakai does not cure the defects in Gundelfinger. In particular, Sakai is cited as teaching "a carrier/bead transporting apparatus for use in an immunological analysis which supplies and/or discharges the predetermined number of carrier/beads into and/or from reaction vessels." *See*, page 5 of the Final Office Action mailed 2/17/06. Because Sakai, does not cure the defects in Gundelfinger, the combined references do not teach all of the salient elements of the claims, and therefore the rejection is improper.

The arguments as presented above with regard to claims that depend from independent claim 1 are also applicable to claims 28-29, and 33, which depend either directly or indirectly from independent claim 26, and claims 47-48, which depend from independent claim 46.

Because the combination of references does not teach or suggest all of the salient elements of the claims as recited, the Examiner has not established a proper *prima facie* case of obviousness and the rejection is therefore improper.

C. Dependent claims 38-41 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Gundelfinger (U.S. Pat. No. 4,068,528) in view of Lecerf (U.S. Pat. No. 4,705,059).

Claims 38-41 depend either directly or indirectly from independent claim 26, and therefore include all of the limitations of independent claim 26. As discussed above, the Examiner has failed to establish a proper *prima facie* case of obviousness, because Gundelfinger does not teach or suggest all of the elements of independent claim 26. Specifically, Gundelfinger does not teach or suggest 1) a plurality of chambers or 2) a valve body having a fluid processing region coupled fluidicly with a fluid displacement region as explicitly recited by applicants in independent claim 1. Lecerf does not cure the defects in Gundelfinger. In particular, Lecerf is cited as teaching "a fluid dispensing device. The device comprises an energy transmitting member(14) coupled to the fluid processing region (12) through a cover(12)." *See*, page 5 of the Final Office Action mailed 2/17/06.

Because the combination of references does not teach or suggest all of the salient elements of the claims as recited, the Examiner has not established a proper *prima facie* case of obviousness and the rejection is therefore improper.

CONCLUSION

In view of the foregoing arguments distinguishing claims 1-16 and 26-48 over the art of record, Applicants respectfully submit that the claims are in condition for allowance, and respectfully request that the rejection of these claims be reversed.

Respectfully submitted,

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VIII. CLAIMS APPENDIX

1. (original) A fluid control and processing system comprising:

a housing having a plurality of chambers; and

a valve body including a first fluid processing region continuously coupled fluidicly with a fluid displacement region, the fluid displacement region being depressurizable to draw fluid into the fluid displacement region and pressurizable to expel fluid from the fluid displacement region, the valve body including a plurality of external ports, the first fluid processing region being fluidicly coupled with at least two of the external ports, the fluid displacement region being fluidicly coupled with at least one of the external ports of the valve body, and the valve body being adjustable with respect to the housing to allow the external ports to be placed selectively in fluidic communication with the plurality of chambers,

wherein at least one of the plurality of chambers is a processing chamber, the processing chamber including a first port and a second port for selectively communicating with at least one of the external ports of the valve body, the processing chamber providing an additional fluid processing region.

2. (original) The system of claim 1 wherein at least one of the fluid processing regions in the valve body or in the processing chamber contains a fluid processing material which is an enrichment material or a depletion material.

3. (original) The system of claim 2 wherein the fluid processing material comprises at least one solid phase material.

4. (original) The system of claim 3 wherein the solid phase material comprises at least one of beads, fibers, membranes, filter paper, glass wool, polymers, and gels.

5. (original) The system of claim 3 wherein the fluid processing material comprises a filter and beads.

6. (original) The system of claim 3 wherein the fluid processing material comprises at least two types of beads.

7. (original) The system of claim 6 wherein the at least two types of beads perform at least two different functions which are selected from the group consisting of cell capture, cell lysis, binding of analyte, and binding of unwanted material.

8. (original) The system of claim 1 wherein at least one of the fluid processing regions contains a solid phase material which performs at least two different functions selected from the group consisting of cell capture, cell lysis, binding of analyte, and binding of unwanted material.

9. (original) The system of claim 2 wherein the fluid processing material comprises at least one liquid phase material.

10. (original) The system of claim 9 wherein the liquid phase material comprises at least one of ficoll, dextran, polyethylene glycol, and sucrose.

11. (original) The system of claim 2 wherein the fluid processing material is contained in the fluid processing region by one or more frits.

12. (original) The system of claim 1 wherein the external ports are disposed on a generally planar external port surface of the valve body, and wherein the valve body is rotatable around an axis and relative to the plurality of chambers to allow the external ports to be placed selectively in fluidic communication with the plurality of chambers, the axis being perpendicular to the external port surface, and the external ports being spaced from the axis by a common radius.

13. (original) The system of claim 1 wherein at least one of the fluid processing regions contains one type of beads which perform at least two different functions selected from the group consisting of cell capture, cell lysis, binding of analyte, and binding of unwanted material.

14. (original) The system of claim 1 wherein the processing chamber includes a receiving area for receiving a processing module containing an enrichment material or a depletion material.

15. (original) The system of claim 14 wherein the processing chamber further includes a collection area for receiving fluid that has flowed through the processing module, and wherein the processing module includes means for retaining the enrichment or depletion

material in the processing module and a spout for directing the fluid into the collection area.

16. (original) The system of claim 1 wherein at least one of the chambers is a reagent chamber containing dried or lyophilized reagents.

17. (withdrawn)

18 (withdrawn)

19. (withdrawn)

20. (withdrawn)

21. (withdrawn)

22. (withdrawn)

23. (withdrawn)

24. (withdrawn)

25. (withdrawn)

26. (original) A fluid control and processing system comprising:

a housing having a plurality of chambers; and

a valve body including a fluid processing region continuously coupled fluidicly with a fluid displacement region, the fluid displacement region being depressurizable to draw fluid into the fluid displacement region and pressurizable to expel fluid from the fluid displacement region, the valve body including an external port, the fluid processing region being fluidicly coupled with the external port, the fluid displacement region being fluidicly coupled with the external port of the valve body, and the valve body being adjustable with respect to the housing to allow the external port to be placed selectively in fluidic communication with the plurality of chambers.

27. (original) The system of claim 26 wherein the valve body is adjustable with respect to the housing to close the external port so that the fluid displacement region and the fluid processing region are fluidicly isolated from the chambers.

28. (original) The system of claim 26 wherein at least one of the chambers or the fluid processing region contains an enrichment material or a depletion material.

29. (original) The system of claim 28 wherein the enrichment or depletion material perform a function which is selected from the group consisting of cell capture, cell lysis, binding of analyte, and binding of unwanted material.

30. (original) The system of claim 26 wherein at least one of the chambers is a processing chamber having inlet and outlet ports for selectively communicating with the external port of the valve body.

31. (original) The system of claim 30 wherein the processing chamber includes a receiving area for receiving a processing module containing an enrichment material or a depletion material.

32. (original) The system of claim 31 wherein the processing chamber further includes a collection area for receiving fluid that has flowed through the processing module, and wherein the processing module includes means for retaining the enrichment or depletion material in the processing module and a spout for directing the fluid into the collection area.

33. (original) The system of claim 26 wherein at least one of the chambers is a reagent chamber containing dried or lyophilized reagents.

34. (original) The system of claim 26 wherein the fluid displacement region is depressurizable by increasing in volume and is pressurizable by decreasing in volume.

35. (original) The system of claim 34 further comprising a fluid displacement member disposed in the fluid displacement region, the fluid displacement member being movable to adjust the volume of the fluid displacement region.

36. (original) The system of claim 35 wherein the fluid displacement member comprises a piston movable in a linear direction in the fluid displacement region.

37. (original) The system of claim 36 wherein the fluid displacement member comprises a piston shaft which is connected to a distal portion of a piston rod for driving the piston shaft to move inside the fluid displacement region, the piston shaft being smaller in cross-section than the piston rod.

38. (original) The system of claim 26 further comprising an energy transmitting member operatively coupled with the fluid processing region for transmitting energy thereto to process fluid contained therein.

39. (original) The system of claim 38 further comprising a cover disposed between the fluid processing region and the energy transmitting member.

40. (original) The system of claim 39 wherein the cover comprises a rigid shell.

41. (original) The system of claim 39 wherein the energy transmitting member comprises an ultrasonic member for transmitting ultrasonic energy through the cover into the fluid processing region.

42. (original) The system of claim 26 wherein the valve body includes a crossover channel, the valve body being adjustable with respect to the housing to place the crossover channel in fluidic communication with an aspiration chamber and a source chamber to permit aspiration of a fluid from the source chamber through the crossover channel to the aspiration chamber.

43. (original) The system of claim 42 wherein the body is rotatably adjustable around an axis, and wherein the at least one external port is disposed within a range of external port radii from the axis and the crossover channel is disposed within a range of crossover channel radii from the axis, the range of external port radii and the range of crossover channel radii being non-overlapping.

44. (original) The system of claim 43 wherein the crossover channel is a circular arc lying on a common crossover channel radius from the axis.

45. (original) The system of claim 26 wherein at least two of the plurality of chambers are separated by a flexible wall to permit change-over of chamber volumes between the chambers.

46. (original) A fluid control and processing system for controlling fluid flow among a plurality of chambers, the system comprising:

a body including a fluid processing region continuously coupled fluidicly with a fluid displacement region, the fluid displacement region being depressurizable to draw fluid into the fluid displacement region and pressurizable to expel fluid from the fluid displacement region, the body including at least one external port, the fluid processing region being fluidicly coupled with the at least one external port, the fluid displacement region being fluidicly coupled with at least one external port of the valve body, and the body being rotatably adjustable relative to the plurality of

chambers to place the at least one external port selectively in fluidic communication with the plurality of chambers.

47. (original) The system of claim 46 wherein at least one of the chambers or the fluid processing region contains an enrichment material or a depletion material.

48. (original) The system of claim 46 wherein at least one of the chambers is a reagent chamber containing dried or lyophilized reagents.

IX. EVIDENCE APPENDIX

none

X. RELATED PROCEEDINGS APPENDIX

none

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